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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/062,425	02/05/2002	Norihiro Kikukawa	Q68263	4121

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WASHINGTON, DC 20037

EXAMINER

SAUCIER, SANDRA E

ART UNIT	PAPER NUMBER
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1651

DATE MAILED: 07/03/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.
10/062,425

Applicant(s)
Kikukawa et al.

Examiner
Sandra Saucier

Art Unit
1651



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

Claims 1-10 are pending and are considered on the merits.

Claim Rejections – 35 USC § 112

INDEFINITE

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is confusing and lacks active method steps, adding, mixing, etc.. Please rephrase to clarify what is being added to what.

Claims 4 and 5 lack antecedent basis for “the extraction..” and “the freeze drying”. It is also unclear if these are further steps intended to be added to the process.

Claim 7 is a composition claim which states in the preamble that it is a thromboplastin reagent. However, it appears that a substance such as glycine, glutamate, glutamic acid is the only component required in the composition.

In the interest of compact prosecution, the method claim is interpreted to be: A method for the manufacture of a thromboplastin reagent comprising: adding an amino acid or amino acid derivative to thromboplastin in order to produce a thromboplastin composition which has an ISI nearer to 1.0.

The composition claims are interpreted to have thromboplastin and amino acid or amino acid derivative.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action: A person shall be entitled to a patent unless (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by GB 872,536 [N].

The claims are directed to a method of making a thromboplastin reagent

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comprising adding an amino acid or derivative thereof (glycine, glutamic acid, sodium glutamate) to thromboplastin and the product thereof.

The kit claim requires only thromboplastin and glycine, glutamate or glutamic acid.

The references are relied upon as explained below.

GB 872,536 teaches the addition of 0.3M glycine to thromboplastin.

Although the intended use of the composition of '536 is not the same as the presently claimed composition, the components are the same, namely 0.3M glycine and thromboplastin. ISI values are an inherent property of the composition. It is reasonable to expect when the same amount of glycine is added to thromboplastin as disclosed in the prior art of '536, if the composition were subsequently tested for ISI value, the composition after addition of glycine would have a lower ISI value. This is because the same one step method of adding glycine to thromboplastin is performed; therefore, the same result (lowering of the ISI value) is reasonably expected.

Claims 1–10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by US 4,416,812 [A] or US 5,270,451 [B].

The claims have been discussed above.

US 4,416,812 teaches a process where glycine 2% wt is added to a thromboplastin reagent preparation and then the preparation is lyophilized (Example 4).

US 5,270,451 disclose in Example V, thromboplastin solution to which is added 5.25% glycine and then it is lyophilized.

ISI values are an inherent property of the composition as explained above.

Claims 1–10 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by JP 06–337267 [O] or Hardy *et al.* [U].

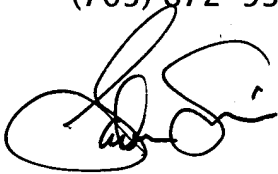
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JP 06-337267 discloses a method of making a thromboplastin composition comprising: adding sodium glutamate to a thromboplastin solution and freeze drying (Example 3).

Hardy *et al.* disclose the addition of 0.001-10% glutamic acid to thrombokinese (thromboplastin).

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. **Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198.** The number of the Fax Center for the faxing of official papers is (703) 872-9306 or for after finals (703) 872-9307.



Sandra Saucier
Primary Examiner
Art Unit 1651
June 30, 2003